UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
KATHY L. BATTY,	)	
Plaintiff,	)	
v.	)	**No. 12 C 6279**
ZIMMER, INC., ZIMMER HOLDINGS, INC., and ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Kathy Batty and more than 1500 other plaintiffs have sued Defendants, Zimmer, Inc. and its affiliates (collectively, "Defendant" or "Zimmer"), manufacturers of the Zimmer NexGen Flex Knee system. Batty and the other Plaintiffs have had the NexGen Flex system implanted in their bodies, and allege here that the system's femoral and tibial components are prone to premature loosening—resulting in pain and loss of movement. Ms. Batty's case has been chosen for a "bellwether" trial. Both parties have identified several expert witnesses. In earlier rulings, the court resolved challenges to three of Ms. Batty's proposed experts, Dr. Thomas Brown and Dr. Joseph Fetto [1536],[1] and her treating physician, Dr. Alan Klein [1539]. The court has also resolved challenges to two of Zimmer's experts, Dr. Darryl D'Lima [1557], and Dr. Michael Vitale [1563], denying Plaintiff's motions to exclude their proposed testimony. Most recently, the court sustained Plaintiff's objections to testimony of Dr. Stuart Goodman concerning Ms. Batty's knee alignment and granted in part and denied in part her motion to bar

[1] All docket citations are to the "lead" docket, In re Zimmer NexGen Knee Implant Products Liability Litigation, No. 11-cv-5468.

certain testimony of Dr. Timothy Wright [1575]. Here, the court considers objections to the expert testimony of Plaintiff's expert, Dr. George Samaras [1304], and Zimmer's expert, Timothy Ulatowski [1327], both of whom have offered opinions about Zimmer's compliance with the FDA regulatory process.

Plaintiff retained Samaras, a multi-disciplined engineer and medical device consultant with more than 40 years of work experience, to provide opinions related to: (a) Zimmer's pre-market design processes for the NexGen Flex system; (b) Zimmer's conduct in obtaining regulatory approval for that system; and (c) Zimmer's post-market product monitoring. (Pl. Resp. to Def. Mot. to Exclude Samaras [1453], hereinafter "Pl. Resp. to Samaras", 1.) Samaras holds the opinion that Zimmer "failed to comply with generally-accepted quality management principles and practices" in its pre- and post-market conduct, and that those failures contributed directly to Ms. Batty's injuries. (Exp. Rep. of Dr. Samaras, Ex. A to Mot. to Exclude Samaras [1305-1], hereinafter "Samaras Rep.", 3.)

Zimmer retained Mr. Ulatowski, a consultant with 36 years of work experience at the FDA, to provide opinions related to the FDA's process for reviewing the NexGen Flex system and permitting its introduction into the marketplace. (Def. Resp. to Pl. Mot. to Exclude Ulatowski [1451], hereinafter "Def. Resp. to Ulatowski," 1.) Ulatowski also critiques certain opinions offered by Dr. Samaras. (*Id.*)

For the reasons set forth below, both motions are granted in part and denied in part. For purposes of determining liability, the court will not admit expert testimony from either party concerning the FDA's process for clearing medical devices for market. To the extent information about that process is relevant to liability, the court will expect it to be introduced by way of a stipulation. The court reserves ruling on whether such evidence may be admissible to establish or defeat a claim for punitive damages, and also reserves ruling on the evidence related to Zimmer's post-market monitoring of its devices, pending further proceedings.

BACKGROUND[2]

Ms. Batty suffers from degenerative joint disease in both knees. In April 2009, her treating physician, Dr. Alan Klein, performed total knee replacements on both of Ms. Batty's knees. Dr. Klein implanted a NexGen LPS-Flex Gender Solutions femoral component (the "NexGen Flex") and a NexGen Stemmed Tibial Component Option in each knee. These components, two models at issue in these lawsuits, are designed to enhance a patient's flexion capacity to 155 degrees, significantly more than earlier implants, including Zimmer's own well-regarded original knee implant model (the "NexGen Standard"). Just over a year after her surgeries, in July 2010, Ms. Batty began to experience pain in both knees. She had the implants replaced in April and May of 2011.

Ms. Batty filed this Pennsylvania state law products liability suit in July 2012, alleging that the NexGen Flex design caused the implants to prematurely loosen from the bone by increasing the forces and strain placed on the implant. She brought several state causes of actions for design defect, strict liability, and failure to warn. The court granted summary judgment in favor of Zimmer on the strict liability claims, but denied summary judgment on her negligence-based design defect claim. *See In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3669933, *2 (N.D. Ill. June 12, 2015). The court concluded that "[m]aterial fact questions remain[ed] concerning whether Zimmer exercised reasonable care designing its NexGen Flex knee, drafting warnings to accompany the device, and other conduct associated with monitoring the device after it was placed on the market." *Id.* at *34. The court now turns to the parties' proposed witnesses concerning the FDA review process.

[2] The facts of Ms. Batty's case are revisited briefly here to provide context for the issues to be decided by the jury at her bellwether trial. Still, this opinion assumes familiarity with the facts and procedural history described in earlier opinions. *See In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3669933 (N.D. Ill. June 12, 2015); *In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3799534 (N.D. Ill. June 17, 2015).

DISCUSSION[3]

I. Dr. Samaras: Overview

Plaintiff's proposed expert, Dr. George Samaras, has doctoral degrees in physiology and industrial engineering and holds professional licenses and certificates in several engineering disciplines, including electrical, software, human factors,[4] and quality systems.[5] (Samaras Rep. at 3; Samaras CV, Appx. B to Samaras Rep., hereinafter "Samaras CV.") Samaras has worked with regulated medical device firms since 1996, performing consulting work related to engineering management, technique, and regulatory compliance. (Samaras Rep. at 3.) For two years in the mid-1990s, he worked for the FDA, where his responsibilities included reviewing engineering aspects of medical devices and software and drafting industry guidance for computer software validation and ophthalmic lasers systems.[6] (Samaras CV.) He did not conduct field inspections of medical device manufacturers while at the FDA, however, nor did he receive training on such inspections. (*See* Dep. of Dr. Samaras, Ex. C to Pl. Resp. [1453-4], hereinafter "Samaras Dep.", 89:18–90:12.)

Over the course of his career, Dr. Samaras has taught graduate classes in engineering and biomedicine and has conducted research on various industrial engineering topics. (Samaras CV.) Most recently, he was a visiting research professor at Colorado State University-Pueblo, from the fall of 2010 through 2013; his *curriculum vitae* does not identify the

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[3] The court has laid out the *Daubert* standards in an earlier opinion, *see In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3669933, at *6–7 (N.D. Ill. June 12, 2015), and declines to repeat them here.

[4] Dr. Samaras defines "human factors engineering" as "the engineering and study of the interface between individual humans or groups of humans (organizations) and their tools," with "tools" being broad enough to include medical devices. (Samaras Supp. Rep., Ex. M to Def. Mot. to Exclude Samaras [1305-13], hereinafter "Samaras Supp. Rep.", 17.)

[5] Federal regulations define a "quality system" as "the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management." 21 C.F.R. § 820.3(s).

[6] Ophthalmic lasers are used for different types of eye surgeries. (Samaras Dep. at 56:21–23.)

nature of his research or any courses he taught there. (*Id.*) He did teach courses in project management and ergonomics as an adjunct professor at the University of Southern Colorado in 1997 and 1998. (*Id.*) In the early 1990s, Dr. Samaras taught graduate-level courses in marketing and entrepreneurial management at George Washington University and researched topics in industrial engineering. (*Id.*) His other academic experience dates from the late 1970s and early 1980s, at the University of Maryland School of Medicine, where he researched biomedical engineering issues related to brain tumors and esophageal cancer and taught graduate-level courses on physiology, biophysics, and applied biomedical engineering. (Samaras CV.) In formulating his opinions, Dr. Samaras states that he examined Zimmer's internal documents, depositions, and various academic articles using his "knowledge, training and experience as a biomedical scientist and interdisciplinary engineer (electrical software, industrial, human factors, and quality) with medical device regulatory experience[.]" (Samaras Rep. at 3; Appx. A to Samaras Rep. at 63–156.)

Dr. Samaras has submitted both an expert report and a supplemental report. The text of his initial report, excluding appendices, is some 60 pages, single-spaced, with 241 footnotes. (*See generally* Samaras Rep.) The supplemental report, to which the parties have made almost no reference at all, contains another some 20 pages of text alone, again single-spaced, and an additional 95 footnotes. (*See generally* Samaras Supp. Rep.) Including appendices, Dr. Samaras's reports together comprise a dismaying 250 pages, far more than any jury or judge can reasonably be expected to digest. The court has devoted substantial effort to wading through these reports and attempting to locate sources he cites, including academic studies, Zimmer's submissions to the FDA, and general engineering textbooks. Some documents are referred to by Bates-stamp, but are not in the record at all, leaving the court to guess at their contents.

The parties themselves have struggled to distill Dr. Samaras's proposed testimony into workable components. For example, Zimmer has identified 17 distinct opinions offered by Dr.

Samaras, and asks the court to sustain its objection to those opinions if Dr. Samaras' testimony is not excluded in its entirety. (*See* Mot. to Exclude Samaras [1304], ¶¶ 1–17.) Plaintiff, on the other hand, sees Dr. Samaras as offering opinions concerning three general topic areas: (1) Zimmer's pre-market conduct; (2) Zimmer's conduct in obtaining regulatory approval for the devices; and (3) Zimmer's post-market vigilance in monitoring the performance of the devices once they were implanted into humans. (*See* Pl. Resp. at 1; Samaras Rep. at 8.) The parties' briefs speak past each other more often than not. The court cautions that this unwieldly record invites confusion and error, and urges counsel to exercise greater control over their experts' submissions.

Samaras has offered conclusions that are broad, non-specific, and too often leave the impression that he is not engaged in neutral expert analysis, but instead on a mission to find fault with Zimmer's conduct in all matters related to the NexGen Flex system. Here, for instance, is his two-paragraph synopsis of his "overarching conclusion" as it relates to Zimmer's pre- and post-market activities concerning the NexGen Flex system:

> Zimmer fell well below the standard of care expected of manufacturers of implantable medical devices. Zimmer failed to comply with generally-accepted quality management principles and practices. The failures to rigorously implement design controls and risk management prior to marketing in the US prevented Zimmer from identifying human errors and design defects in their new product development efforts. Zimmer failed to disclose the errors and defects to the regulator as part of their premarket notification. Zimmer failed to provide effective warnings to physicians and patients regarding new risks inherent in the use of the implants; they failed to provide effective training for surgeons, since they claim that standard surgical technique was inadequate for use with their implants. Instead, Zimmer marketed the NexGen Flex knee implants as an improvement without new risks, claiming they would safely accommodate high flexion.
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> The failures to effectively warn and to effectively train can be traced back directly to failures to correctly implement premarket design controls and risk management, which are fundamental elements of quality engineering. Misrepresentations and omissions in the premarket notifications prevented the regulator from recognizing defective quality engineering, thus undermining the ability of the regulator to take prompt action to protect the public health. Failures in postmarket vigilance (complaint handling, health hazard evaluation, adverse events reporting, and corrective and preventive actions) can also be traced to defective quality engineering throughout the product lifecycle.

(Samaras Rep. at 4.) His supplemental report includes additional support for this omnibus conclusion and includes criticisms of Zimmer's experts. Of those, Dr. Ulatowski is the only expert involved in Ms. Batty's case, however, so the court reserves ruling on the admissibility of Dr. Samaras's critiques of the opinions offered by Dr. David Feigal, Dr. Steven Kurtz, and Dr. Jorge Ochoa. (*See generally* Samaras Supp. Rep.) Before it undertakes that effort, the court will expect counsel to review Dr. Samaras's supplemental report and reduce it to brief and well-supported statements of specific opinions.

The court turns now to *Daubert*'s three-step inquiry, beginning with Dr. Samaras' qualifications.

A. *Daubert*: Qualifications

Zimmer argues that Dr. Samaras lacks relevant expertise to criticize Zimmer's design choices and pre-market and post-market conduct associated with the NexGen Flex system. (Def. Samaras Mem. [1305], 1–2.) The federal regulations that govern Zimmer's engineering quality systems in this case, Zimmer notes, do not include "specific, prescriptive information about how to make a device," but are instead written broadly to apply to a wide range of device types. (*Id.* at 2 (citing *See* 21 C.F.R. § 820 *et seq.*).) Zimmer urges, therefore, that because Dr. Samaras lacks "substantive expertise about the device being designed," he is not qualified to opine on Zimmer's conduct in developing the NexGen Flex implant series. (*Id.*) That is, "Dr. Samaras tries to condemn the Zimmer Quality System from the perspective of an external auditor or design engineer, despite his lack of expertise with any of the specialized scientific, engineering, and medical areas involved in orthopedic product design." (*Id.* at 4.) And, Zimmer notes, Dr. Samaras lacks expertise concerning the medical device regulatory process and appropriate post-market monitoring strategies. (Def. Samaras Mem. at 16, 21.)

Zimmer's arguments have merit, and the court discusses specific concerns about Dr. Samaras's qualifications below. The court declines the invitation to reject Dr. Samaras on the

basis of Zimmer's objections to his qualifications only, however. For one, "[t]he notion that [*Daubert*] requires particular credentials for an expert witness is radically unsound." *Tuf Racing Prods., Inc. v. Am. Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000). Instead, anyone with "relevant expertise" is allowed to testify if the expert otherwise satisfies the federal expert-witness requirements. *Id.* Dr. Samaras does have such expertise, at least as it pertains to high-level analysis of engineering processes themselves: as described above, he has doctoral degrees in engineering management and physiology and 40 years of experience as an engineer working in various disciplines. (*See* Samaras CV.) Of course, knowledge of the science underlying such systems (i.e., implantable medical devices) might well enable Dr. Samaras to provide more credible critiques. Plaintiff appears to recognize the limits of Dr. Samaras' expertise, however, and has cabined his testimony to the engineering processes and systems involved in designing the implant, without venturing into criticism about the NexGen Flex design itself. (*See* Samaras Dep. at 318:9–12 ("My opinion [addresses] the engineering processes involved in the development and post-market vigilance, not in the clinical issues regarding the products and its use."); *id.* at 16–21 ("Q. [A]re you intending to express any opinion that there was a defect in any Zimmer product that went out the door? A. I've not been asked to give an opinion on the design of the product. So presumably the answer would be no, then.").) If Dr. Samaras is able to reliably support his opinion concerning Zimmer's various engineering processes with a plausible methodology, the fact that his testimony will be limited to opinions on those processes poses no obstacle to admissibility.

Nor is the court persuaded that Dr. Samaras cannot testify on the pre- and post-market conduct associated with the NexGen Flex series because he is not a physician—and specifically not an orthopedic surgeon. Rule 702 allows experts to testify who may be qualified by "knowledge, skill, [and] experience" as opposed to education and job credentials alone. To the extent knowledge of the underlying device would improve his analysis, these alleged shortcomings are proper fodder for cross-examination. *See Daubert*, 509 U.S. at 596

("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). In sum, Zimmer's wholesale objection to Samaras' testimony on the basis of lack of engineering experience is overruled.

B. Reliability

Zimmer contends that Dr. Samaras has not based his opinions on any reliable methodology and moves to exclude all of his testimony on this ground. In addition, Zimmer teases out 17 distinct opinions Samaras offers, arguing that if its motion is not fully granted, each of these individual opinions should be excluded as unreliable. (*See* Mot. to Exclude Samaras at 2–3, ¶¶ 1–17.). Rather than address Dr. Samaras' conclusions piecemeal, the court follows Plaintiff Batty's lead and addresses his conclusions as falling into the three general areas identified earlier: (1) Zimmer's pre-market conduct; (2) Zimmer's regulatory approval process; and (3) Zimmer's post-market monitoring of the devices. (*See* Pl. Resp. at 1; Samaras Rep. at 8.)

1. Pre-Market Conduct

a. Design Inputs

Dr. Samaras alleges that "Zimmer systematically failed to comply with international consensus standards and US federal regulations regarding (a) the control of the design; (b) the management of risk; and (c) the management of personnel involved in the development and quality management of medical devices." (Samaras Rep. at 20.) Dr. Samaras first criticizes the design inputs recorded in Zimmer's design history file for the NexGen Flex Knee system.[7]

[7] The Code of Federal Regulations mandates that "[e]ach manufacturer shall establish and maintain a [design history file] for each type of device." 21 C.F.R. § 820.30. The court cannot locate the design history files in the record, save a few excerpts attached as exhibits to Zimmer's brief accompanying its motion to exclude the testimony of Samaras. (*See* CR Flex Femoral Components 510(k) Excerpt [1305-8], Female Gender Solutions 510(k) Excerpt [1305-9], MIS Tibial Components 510(k) Excerpt [1305-10].) As Zimmer does not specifically challenge Samaras's factual representations about the content of those files, the court will rely on those representations.

Samaras characterizes design inputs as the "foundation of design verifications and the basis for design validation."[8] (*Id.*) Of more than 50 design inputs that appear in the design history file, Dr. Samaras has identified three that he feels are "incomplete and ambiguous" and addresses them in his report. First, he turns to the design input for the Legacy Posterior Stabilized ("LPS") Flex implant, which reads as follows: "The implant shall maintain adequate tibio-femoral contact throughout the flexion range." (*Id.* at 21.) Dr. Samaras takes issue with this wording, claiming "[t]here is no operationalization of what dimensionality is '*adequate*', how tibio-femoral '*contact*' is defined and measured, or what measurements are required for a pass-fail decision." (*Id.* (emphases in original).)

Dr. Samaras critiques two other inputs, as well: for the NexGen CR Flex design, one of its inputs calls for "articular surfaces . . . able to withstand loading conditions induced by high flexion activities." (Samaras Rep. at 21.) He claims there is "no operationalization of the static and dynamic '*loading*' conditions, how '*withstand*' is defined and measured, or what types of high flexion '*activities*' are envisioned (kneeling and sitting crosslegged versus dynamic squatting with and without such loads as exercise weights or work-related loads)." (*Id.*) Similarly, he asserts that the LPS-Flex implant's design input, too, is vague and lacks defined criteria. (*See* Design Input at *id.* ("The geometry of the keel should be designed to provide adequate fixation[.]").)

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[8] Design inputs are "the physical and performance requirements identified by the designers at the beginning of the design process, and [are] used as a basis for device design." (Def. Samaras Mem. at 6.)

Design verification "is an engineering process that . . . is a scientifically-valid experiment to demonstrate that each design output faithfully conforms, completely and correctly, to its corresponding operationalized design input." (Samaras Rep. at 21.)

Design validation "is an engineering process that . . . is a scientifically-valid experiment to demonstrate that the whole device meets the design inputs (the selected stakeholder needs) for the intended use in the intended use environment (or a fair simulation, thereof)." (*Id.* at 25.)

The methodology underlying these criticisms is lost on the court. Samaras claims that Zimmer's inputs violate "ISO 9001, ISO 13485,[9] and 21 C.F.R. § 820.30(c)" because they are incomplete and ambiguous, but he does not elaborate on how the inputs fall short of these standards. The relevant federal regulation, 21 C.F.R. § 820.30(c), reads as follows:

> (c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. *The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements*. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(emphasis added). Indeed, the regulation requires the procedures, or the design inputs, to "include a mechanism for addressing incomplete, ambiguous, or conflicting requirements." But Samaras simply declares that several of Zimmer's inputs are "ambiguous," without explaining, for example, whether orthopedic implant designers—the relevant target audience for the design inputs—would find such terms vague, or whether industry practices provide context for the terms. Dr. Samaras might have clarified his view by offering examples of what he deems adequate design inputs, but he has not done so, and the court therefore has no reference points to judge his conclusions.

Also troubling is Dr. Samaras' decision, having reportedly examined all of the 50-plus design inputs for the NexGen Flex series, to "pick[] three to write up just as examples –

[9] "ISO" refers to the International Organization for Standardization, a worldwide federation of national standards bodies that work to draft international standards for certain industries. (*See* Foreword to ISO Standards Application of Risk Management to Medical Devices, Ex. L to Def. Samaras Mem. [1305-12].) Dr. Samaras defines ISO 9001 as a "general standard defining the requirements of quality management systems applicable to suppliers of all product types." (Samaras Rep. at 12.) ISO 13485, he asserts, "is an independent particular standard, derived from ISO 9001, defining the particular requirements of quality management systems for suppliers of products that are medical devices." (*Id.*) Unfortunately, Samaras provides only cursory citations to subsections of these ISO standards throughout his report and deposition. An expert should provide a clear roadmap from standards or principles to application of such rules to the device at issue. Simply claiming that Zimmer violated "ISO 9001" or "ISO 13485," as he did above, sheds little light on the issues. *Cf. Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 773 (7th Cir. 2014) ("[A]n expert must do more than just state that []he is applying a respected methodology; []he must follow through with it.").

exemplars of the criticisms that I had." (Samaras Dep. at 127:1–5.) When asked whether there were at least some design inputs that he considered adequate, Samaras conceded that there "probably" are, but frankly acknowledged that his report was not intended "to tell you all the wonderful things Zimmer did. I'm trying to tell you the mistakes they did." (*Id.* at 128:10–129:1.) Such a nakedly partisan view of the role of an expert is disappointing. And more substantively, the court notes that Dr. Samaras never explains what criteria he used to (1) judge the adequacy of each design input; or (2) determine how many "inadequate" design inputs were enough to contaminate the entire design process. This is confounding; part of the court's analysis requires a determination "that the expert considered sufficient data to employ the methodology," *Stollings*, 725 F.3d at 766, and it is not enough for the expert simply to declare that his opinion is based on his "knowledge and experience as a biomedical scientist, an interdisciplinary engineer, and former medical device regulator." (Samaras Rep. at 59.) Expert testimony may not be simple guess-work or *ipse dixit*, and he must do more than simply declare he is "applying a respected methodology; [Dr. Samaras] must follow through with it." *Brown*, 765 F.3d at 773.

Further undermining the reliability of his opinions is Dr. Samaras' admission that he is not qualified to explain what *would* constitute an adequate design input. For example, in the LPS-Flex design input discussed above, Dr. Samaras claims the terms are "incomplete and ambiguous" because the inputs do not define "adequate" nor explain how contact is to be measured. Without further explanation, the court is uncertain how that opinion is a product of Dr. Samaras's expertise. Presumably, a lawyer or other non-technical expert could scour these input terms in a vacuum, probing for lexical vagueness. When asked at his deposition what a "proper design input" would be for this example, Samaras conceded he does not have one because he is "not an orthopedic design engineer." (Samaras Dep. at 129:11–21.) He gave the same response for the other two examples offered. (*See id.* at 132:21–25; 133:18–22.) And when asked to explain one of these terms ("adequate tibio-femoral contact"), Samaras conceded that he did not know what that phrase means to orthopedic engineer designers. (*Id.*

at 193:2–12.) Dr. Samaras' criticisms of Zimmer's failure to offer definitions or standards lose force in the absence of any suggested adequate alternatives—a failure that appears to result from the fact that, as he admits, he is not an orthopedic design engineer. At least in this regard, his lack of qualifications precludes him from satisfying the reliability prong of the *Daubert* analysis. *See Myers*, 629 F.3d at 644. There are likely some circumstances where an expert's failure to posit an alternative design input would not be troublesome, but Samaras' inability to do so in these circumstances exposes methodological deficiencies. And even if the court were satisfied that Dr. Samaras' methodology is sufficiently reliable, it is not clear how this testimony would be helpful to the trier of fact in understanding what sorts of design inputs would satisfy Zimmer's duty of care; Samaras admits he is not qualified to opine on the sorts of industry-specific terms that could constitute satisfactory design inputs. *Cf. Myers*, 628 F.3d at 644; FED. R. EVID. 702(a).

Compounding the court's concerns about Dr. Samaras' method for selecting design inputs he deems inadequate, he kept no notes nor otherwise tracked which design inputs, if any, he considered adequate, instead selecting examples "that were the most obvious in terms of a defect." (Samaras Dep. at 135:1–12.) It is hard to escape the conclusion that Dr. Samaras prepared his analysis wholly aimed at a particular result. While not fatal, *see Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 534 (7th Cir. 2005) (viewing whether the testimony is developed "expressly for purposes of testifying" as one factor to consider in the reliability analysis), that approach undermines confidence that he will offer "responsible opinion testimony" at trial. *Tuf Racing Prods., Inc.*, 223 F.3d at 591. The burden is on Plaintiff to persuade the court that Dr. Samaras' testimony rests on a sufficiently reliable foundation, and that burden has not been met here. *Cf. Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010).

b. Design Verifications

Design verification, according to Dr. Samaras, is "typically, although not always, accomplished by validated bench testing with the appropriate sensitivity, specificity, and

reliability (or even using validated simulation tools, if costs are prohibitive, testing is destructive, or samples are limited)." (Samaras Rep. at 21–22.)

Dr. Samaras claims that Zimmer was deficient in creating its design verifications because it did not write test protocols and have them "reviewed and approved prior to conducting tests," a process that he contends is "not optional." (*Id.* at 22.) As with design inputs, he selects three examples of Zimmer's design verifications from various design history files that he believes were inadequate. First, the LPS-Flex design history file discusses Zimmer's attempt to use software simulation to compare the amount of constraint[10] between LPS and LPS-Flex devices. (*Id.*) Dr. Samaras criticizes the testing described in that document for two reasons: (1) Zimmer only used software simulation to verify the differences in constraint—that is, the "ability of the prosthesis to resist rotary and shear forces" (Samaras Rep. at 22)—instead of conducting physical testing on "an appropriate number of samples" of both the LPS and LPS-Flex systems; and (2) Zimmer did not test the LPS-Flex up to 155 degrees, which is the maximum amount of flexion the Flex is designed to safely allow. (*Id.*) But Dr. Samaras is not qualified to opine on the design verification of the LPS-Flex as it pertains to constraint: He acknowledged that whether the differences in "constraint" between the LPS and LPS-Flex devices (his report does not say whether such differences in fact exist) were "clinically significant" is outside the scope of his expertise. (Samaras Dep. at 139:14–17.) As Samaras lacks experience necessary to explain what sort of design verification strategy for assessing differences in constraint would be acceptable, his testimony will not aid a jury in determining any facts at issue in the case. *See* FED. R. EVID. 702(a). In her brief, Plaintiff claims, without support, that "Dr. Samaras has no obligation to direct Defendant as to wh[at] testing should have been done and the absence of any such analysis does not in any way undermine his opinions." (Pl. Samaras Resp. at 12.) The court disagrees. Samaras may not have an

[10] Constraint, in a total joint replacement context, means "the degree of physical connection between the components of a prosthesis." (Samaras Rep. at 22.)

"obligation" to propose appropriate testing, but the absence of proposed alternative does indeed undermine the value of his testimony.

Further, when asked whether he could cite "any standard or literature" to support his opinion about appropriate testing, Dr. Samaras responded:

> A. Probably not off the top of my head, but I can tell you that engineers have an ethical obligation to protect the public health, and you're not protecting the public health when you don't fully test your claims before you start sticking stuff in people.

(Samaras Dep. at 143:22–144:4.) Whatever rhetorical force the comment may have, it is insufficient in the context of a *Daubert* analysis: Dr. Samaras must do more than simply proclaim what reasonable engineers must do to fulfill their ethical obligations. *Cf. Fuesting*, 421 F.3d at 536 (a plaintiff may not make an "unjustif[ied] extrapolation from an accepted premise to an unfounded conclusion"). Off-the-cuff remarks about a designer's ethical obligations, untethered to any specific standard, risk misleading the jury and confusing the issues. *See* FED. R. EVID. 403. Absent further explanation, in either his deposition or expert report, this design verification testimony is unreliable and too likely to confuse the jury.

The second design verification that draws Dr. Samaras's criticism appears in the design history file from the CR-Flex porous femoral component for uncemented use. That design verification reports the results of an anterior lift test. (Samaras Rep. at 23.) Samaras faults the test design because it included "only cranio-caudal loading" and does not include "anterior-posterior or medio-lateral loading." Dr. Samaras offers no definitions of any of these terms, but baldly asserts that either anterior-posterior or medio-lateral loading (or both; he doesn't say) would have been better measurements. (*Id.*) In addition, he claims that Zimmer's designers "assume[d]" biomechanical problems away through oversimplification, such as "assum[ing] a single anatomical geometry, rather than consulting the appropriate human factors engineering tables to determine the 5th and 95th percentile values." (*Id.*) Another expert in physiology or engineering might comprehend the criticism: the court does not, and doubts that the statement

would be helpful to a jury. Samaras has neither explained what the "human factors engineering tables" are nor provided a reference for the court's self-education. He concludes that Zimmer's "scientifically-invalid" design verifications have "no demonstrable value for ascertaining the safety and effectiveness of the CR-Flex implant for its intended use," but does not elaborate on what would have "demonstrable value" for assessing a device's safety and effectiveness. (*Id.* at 24.) This broad denouncement does not help elucidate the issues involved in this products liability case. *See* FED. R. EVID. 702(a) (Expert testimony is only admissible "if the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue).

The final design verification Samaras addresses, located in the LPS-Flex history file, is a study that attempts to measure the fixation strength of the tibial component for the NexGen Flex series as compared to the Flex's predicate device. (Samaras Rep. at 24.) Dr. Samaras claims that using a Finite Element Analysis[11] here required Zimmer to make assumptions about certain forces; he then criticizes the assumptions Zimmer made as unrealistic, though he concedes that he is not qualified "to characterize how complex or sophisticated the application of finite element analysis is to models of either human knees or human knee replacement devices." (Samaras Dep. at 151:15–19.) Further, he chides Zimmer for its failure to use the FEA results to create an actual experiment, asserting that this "is inherently inconsistent with good engineering." (Samaras Rep. at 25.) Samaras is not qualified to offer this opinion, though: He is unable to suggest how Zimmer should have tested the cemented interfaces, because, again, this is outside his expertise. (Samaras Dep. at 152:5–10.)

[11] As more fully described in the court's ruling on Plaintiff's objection to the testimony of Zimmer's expert, Dr. Darryl D'Lima, a Finite Element Analysis ("FEA") uses a computer modeling program to predict how an implant will function under certain conditions. (*See* Ruling on Pl. *Daubert* Challenge to Testimony of Dr. Darryl D'Lima, Mem. Op. & Order Aug. 13, 2015 [1557].)

In short, as with design inputs, Plaintiff has failed to establish Samaras is qualified, let alone that his methodology is reliable, and therefore his opinions on design verifications must be excluded.

c. Design Validations

Dr. Samaras next takes aim at Zimmer's design validation strategy, asserting that: (a) Zimmer incorrectly used "design outputs" as the basis for validations when "design inputs" are "well known" to be the appropriate variables for design validations; (b) Zimmer used sawbones and cadaveric studies for design validation, when in fact (he insists, citing no authority) such studies can only ever be design verifications; and (c) Zimmer inappropriately attempted to rely on scientific principles and explanations for its changes to product design instead of actually testing those changes. (Samaras Rep. at 26.)

As he did with design inputs and design validations, Samaras selects three examples of Zimmer's design validation processes and proceeds to criticize them on several fronts. (*Id.* at 26–27.) His criticisms of these processes share an underlying theme: Dr. Samaras does not believe design validation can occur without pre-market clinical trials. (*Id.*) He levels the same criticism, verbatim, at each of the three examples: "The data from the various registries throughout the world that collected post-implant data are not an adequate substitute for premarket design validation." (*Id.* at 27.) He doesn't say why; and this section of his report is replete with background premises left unexplained and unsupported. For instance, the following statement expresses Samaras's general opinion concerning Zimmer's design validation strategy, which used cadaveric studies instead of clinical trials for testing the NexGen Flex devices:

> Until such time as a cadaver rises and walks about the lab with a reasonable facsimile of a human gait, applying the full spectrum of reasonably-expected human biomechanical loads to the prosthesis, its use remains a design verification (primarily of the surgical instrumentation, cementing techniques, etc.), not design validation.

(Samaras Rep. at 26.) The court is at a loss to understand how Dr. Samaras, who elsewhere testified that any type of clinical study is outside the scope of his expertise (*see, e.g.*, Samaras Dep. at 157:20–158:4), has arrived at this opinion. In his deposition, he admitted that the basis for this opinion is "not a citation" but "first principles of physics and biology." (*Id.* at 158:12–14.) He claims his observation is not "conjecture or hypothesis" but a "statement of fact." (*Id.* at 160:13–14.) Respectfully, in the court's view, the statement that cadaveric studies cannot qualify as design validation is one of opinion, not fact. In any event, without supporting authority or an explanation of the basis for that statement, the court is unable to follow how he reached his conclusion. *Wendler & Ezra, P.C. v. Am. Int'l Grp.*, Inc., 521 F.3d 790, 791 (7th Cir. 2008). The court notes that FDA regulations require medical device manufacturers to test their devices "under actual *or simulated* use conditions." 21 C.F.R. § 820.30(g) (emphasis added). And, the court is hesitant to credit Samaras's bold pronouncement about the need for clinical trials to test knee replacement system components; such testing implicates a myriad of public health issues that Samaras has not addressed. *See* Ethics in Clinical Research Guidelines, http://clinicalcenter.nih.gov/recruit/ethics.html (last visited August 26, 2015). In any event, Plaintiff makes no argument that 21 C.F.R. § 820.30(g) does not apply, and its language appears to rebut Dr. Samaras' alleged factual assertion that design validation can *under no circumstances* be achieved through means other than clinical studies.

The court concludes that Dr. Samaras has not provided a reliable basis for his opinions on design validations, and declines to admit those opinions at trial.

d. Other Pre-Market Conduct

Dr. Samaras' remaining opinions on Zimmer's pre-market conduct merit only brief discussion. Dr. Samaras testifies that if Zimmer had conducted a randomized controlled clinical study of the NexGen Flex series, the device would have "failed" such testing and would not have been validated. (*See* Samaras Dep. at 165:7–21.) But Samaras refused to propose any particular design of the testing that he claims the Flex would have failed. Instead, he believes

any "fair test, properly designed, statistically analyzed correctly, given the instructions for use and the surgical technique and everything else that was done for the folks out in the wild" would have failed design validation. (*Id.* at 166:1–5.) He makes no effort to elaborate on this opinion about clinical studies (a matter he concedes is outside his scope of expertise), basing it purely on his "phenomenological" assessment of the devices "in the wild." (*Id.* at 168:1–169:3.) In other words, because (unidentified) "articles in the medical literature" have shown that Zimmer's NexGen Flex devices are prone to aseptic loosening, Samaras is confident that any clinical study that Zimmer conducted would have revealed this result. (Samaras Dep. at 169:4–21.) Elsewhere, he claims that "[h]ad Zimmer followed the correct design and development controls, Zimmer's procedures would have caused it to reject the design of the NexGen Knee implants as deficient." (Samaras Rep. at 59.) But in his deposition he backs away from this claim, insisting that he is not "predicting the results of things that weren't done." (Samaras Dep. at 322:1–2.) The court takes Dr. Samaras at his word here and disallows any testimony from him that attempts to speculate on the results of hypothetical clinical studies.

e. Risk Management

Zimmer did not properly monitor risk in developing the NexGen Flex System, Samaras next asserts. In particular, he states that Zimmer did not adequately consider "known and foreseeable risks to end users," did not estimate the risk of its design correctly, did not have adequate risk control measures in place, and did not have risk control verifications to monitor its risk control measures. (Samaras Rep. at 5.)

The court concludes that material gaps in Dr. Samaras' qualifications, his opinions, and his methodology preclude him from testifying on this issue, as well. First, Dr. Samaras himself admitted that "clinical risk-benefit analysis" is outside the scope of his practice. (Samaras Dep. at 312:19–25.) Without a working understanding of clinical risk-benefit analysis, Samaras has not shown how he is qualified to apply ISO 14971:2000(E), which he identifies as the "consensus standard on risk management for medical devices." (Samaras Rep. at 35.) That

standard specifically calls for people who perform risk management tasks to have "knowledge and experience appropriate to the tasks assigned to them," including, "where appropriate, knowledge and experience of the medical device and its use and risk management techniques." (ISO 14971:2000(E) ¶ 3.4, Ex. L to Samaras Mem. [1305-12], 5.) Under that standard, a risk management expert need not necessarily have "knowledge or experience" of the specific medical device at issue in every case. But Dr. Samaras has not presented a reliable foundation for his opinion on Zimmer's risk management strategy here. Under the regulation he refers to, ISO 14971:2000 ¶ 4.4, risk estimation can be "quantitative or qualitative," *id.*, but Samaras concedes he is not qualified to make a quantitative estimate on risk. (Samaras Dep. at 311:22–312:25.) As for qualitative risk assessments, his report is utterly bereft of foundation, beyond vague conclusory statements that Zimmer did not have "adequate" risk control measures and did not "adequately" consider foreseeable risks to users. (Samaras Rep. at 35–36.) Also troubling is the fact that Dr. Samaras cannot identify any "unacceptable" risk for the NexGen Flex series—that is, what level of risk transgresses the risk management standard—as it is outside his expertise. (Samaras Dep. at 311:22–312:25.) Here again, Samaras's proposed testimony would not "help the trier of fact to understand the evidence or to determine a fact in issue," as required by FED. R. EVID. 702(a).

III. Timothy A. Ulatowski

Zimmer proposes to call Timothy Ulatowski to testify concerning Zimmer's compliance with the FDA regulatory processes. The court considers that proposed testimony together with the testimony Dr. Samaras seeks to offer on the issue. Before doing so, the court pauses to note disappointment with the presentation of Mr. Ulatowski's opinions, as well. Like Dr. Samaras' report, Mr. Ulatowski's report is unreasonably lengthy: 108 pages long, double-spaced, and annotated with 252 footnotes. (*See* Exp. Rep. of Timothy A. Ulatowski, Ex. A to Becker Aff. [1329-1], hereinafter "Ulatowski Rep".) The court devoted substantial resources to reading his report and determining what testimony, if any, he will be allowed to offer. The court

expects the parties to reign in such submissions in the future. It is unfair to both the court and the parties to attempt to digest this much information for issues not obviously relevant to a single-plaintiff products liability case involving non-preempted state law causes of action. The substance of his opinions could have been discussed exhaustively using half as many words or pages.

Zimmer represents that it has retained Mr. Ulatowski to "testify about the FDA regulations applicable to 510(k) submissions and about how Zimmer conducted itself in developing and marketing the NexGen products in light of those regulations." (Def. Resp. to Pl. Mot. to Exclude Ulatowski, hereinafter "Def. Resp." [1451], 4.) Plaintiff contends, however, that Zimmer's characterizations of Ulatowski's proposed testimony are misleading: in fact, they urge, Ulatowski is being offered to establish that "FDA 510(k) clearance is a determination of safety and effectiveness." (Mem. in Supp. of Mot. to Exclude Proposed Testimony of Timothy A. Ulatowski, hereinafter "Pl. Ulatowski Mem." [1328], 2.) Any remaining opinion Ulatowski seeks to offer, Plaintiff continues, is impermissible narrative concerning FDA processes, not expert testimony. (*Id.* at 14–15.)

Rejecting this characterization of Ulatowski's opinions, Zimmer maintains that it "does not claim or offer Mr. Ulatowski to testify that the 510(k) process represents a final legal determination of safety and effectiveness that preempts or otherwise legally forecloses Plaintiffs' claims here." (Def. Resp. at 4.) Given this concession, it is unclear to the court why the jury should hear Ulatowski "explain the process by which FDA reviewed the NexGen devices and the context in which these products were developed," as Zimmer suggests. (Def. Resp. at 1.) In any event, the court sustains Plaintiff's objections to much of his testimony for the reasons explained below.

A. *Daubert*: Qualifications

Mr. Ulatowski has a B.A. in mcrobiology from Pennsylvania State University and a M.S. in physiology with an emphasis in biomedical engineering from Georgetown University.

(Ulatowski Rep. at 1.) He worked at the FDA for 36 years, beginning in 1974 and continuing until 2011, when he retired. (*Id.*) Over that time, he occupied various roles at the agency: he began as a staff laboratory analyst reviewing proposed new drug compounds, and later became an investigator in the Office of Device Evaluation, where he reviewed applications of manufacturers seeking to conduct clinical studies of new medical devices. (*Id.* at 1–2.) He assumed various leadership positions at the agency, as well, and was appointed director in the Office of Device Evaluation in 1996. (Ulatowski CV, Ex. A to Ulatowski Rep.) In this position, he "[m]anaged premarket activities, such as review of premarket submissions and investigational applications" and was the "[p]rimary reviewer on numerous 510(k)s, [Investigational Device Exemptions], and [Premarket Approval Applications]." (*Id.*)

From 2003 until his retirement in 2011, Ulatowski was the director of the Office of Compliance in the Center for Devices and Radiological Health, responsible for "[d]irect[ing] FDA device quality system and bioresearch enforcement programs," and for managing device recalls and device reporting by manufacturers. (*Id.*) Mr. Ulatowski's report and accompanying curriculum vitae together contain much more information about his background and experience while at the FDA, as well, which the court need not review here in detail. Since his retirement, Mr. Ulatowski has served as a consultant on issues related to the FDA and has provided expert testimony in several cases. (*Id.*)

B. *Daubert*: Reliability

1. Narrative Summary

A large portion of Mr. Ulatowski's report consists of a narrative description of the FDA's processes for regulation of medical devices, its 510(k) process in general, an overview of artificial knee devices, and the history of Zimmer's 510(k) submissions for its NexGen Flex system components. (*See generally id.* at 7–25.) The court agrees with Plaintiff that to the extent such information is useful, it should be presented to the jury through a fact witness or (as the court would prefer) by way of a stipulation. *See* FED. R. EVID. 702(a) (expert testimony is

admissible only if "*the expert's scientific, technical, or other specialized knowledge* will help the trier of fact to understand the evidence or to determine a fact in issue") (emphasis added); *see In re Fosamax Products Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding opinions of expert in products liability case that merely offered a "narrative history" of the drug at issue and a "narrative of select regulatory events through the summary or selective quotation from internal [manufacturer] documents, regulatory filings, and the deposition testimony of [manufacturer] employees"). Plaintiff's objections to this narrative testimony are, therefore, sustained.

The court turns now to address the substance of Mr. Ulatowski's testimony, combining that analysis with consideration of certain of Dr. Samaras' opinions relating to the § 510(k) process. (*See* Samaras Rep. at 42–47; Ulatowski Rep. at 7–56.)

IV. FDA 510(k) Process: Proposed Opinions of Ulatowski and Samaras

A. The Import of 510(k) Clearance

The central debate between the two experts focuses on whether 510(k) clearance establishes the safety and effectiveness of a particular device. Samaras maintains that "[t]he FDA's administrative decision, as it related to 510(k) clearance, is focused on equivalence, not safety," and that a 510(k) review does not include a safety determination. (Samaras Rep. at 3–4.) Significantly, the court understands that Plaintiff has offered this opinion related to 510(k) clearance "in rebuttal to the positions of Defendant's experts," specifically Ulatowski and Dr. David Feigal.[12] (Pl. Samaras Resp. at 20–21; *see* Samaras Supp. Rep. at 3 ("While I also reference FDA regulations in my first report, the emphasis of that report is not regulatory opinions . . . While I am well-versed and qualified in FDA regulations and regulatory compliance, regulatory opinions are not germane to . . . to the actual safety, effectiveness, and usability of Zimmer's products.").) Plaintiff's primary argument is that what 510(k) clearance

[12] Dr. David Feigal is not being offered as an expert for Ms. Batty's trial, and the court reserves ruling on the admissibility of his opinions, should they be offered in other trials.

means in terms of safety and effectiveness is a legal determination, but that regardless, it does not involve a determination of safety and effectiveness. (Pl. Samaras Resp. at 20–21.)

Ulatowski disagrees with Samaras's characterization of the 510(k) process and offers eight reasons, based on his review of Zimmer's documents and his "experience, knowledge, and training" (Ulatowski Rep. at 25), why, as he understand the process, the FDA does consider safety and effectiveness in its review of a 510(k) submission:

> First, the content of 510(k)s for knee implants are substantial scientific and technical submissions, commensurate in most respects to the content of similar types of PMA submissions. Second, FDA itself considers a 510(k) review to be an evaluation of safety and effectiveness of the device. Third, the statutory standard of "valid scientific evidence" applies equally to a PMA and 510(k). Fourth, statute and regulations confirm that a 510(k) review is an evaluation of safety and effectiveness. Fifth, FDA sustained its confidence in the 510(k) process and rejected an external review of the process to which Plaintiff's expert refers. Sixth, FDA cannot find a new device equivalent to an unsafe or ineffective predicate. Seventh, the original classification of knee implants by clinical and scientific consulting experts was predicated on an assessment of the safety and effectiveness of this type of device and Eighth, FDA's review of Orthopedic 510(k)s is thorough and rigorous.

(Ulatowski Rep. at 26.) Ulatowski then proceeds to discuss each of his points in detail in his report. (*See id.* at 27–40.) Ulatowski's discussion substantially quotes from federal law and regulations governing the 510(k) process itself. (*Id.*)

The court itself has reviewed the law governing the 510(k) process and concludes that neither expert accurately describes it. The 1976 Medical Device Amendments "imposed a regime of a detailed federal oversight" of medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under that regime, devices are classified under one of three categories, Class I, II, or III. *Id.* Class I devices include devices such as elastic bandages and examination gloves and are subject only to minimal regulations, called "general controls"—for instance, labeling requirements. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices include knee implants and are subject to "special controls," such as performance standards and postmarket surveillance measures. *See* § 360c(a)(1)(B). Importantly, Class II devices may be marketed without advance approval through a process called "premarket notification," also known as a

510(k) submission or notification. *See Medtronic v. Lohr*, 518 U.S. 470, 477 (1996). The 510(k) clearance process "imposes a limited form of review" on manufacturers of qualifying devices. *Lohr*, 518 U.S. at 478. "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis[.]" *Id.* This is in contrast to Class III devices, which include devices with greater safety risks such as pacemaker equipment and electrical brain current stimulators, and which must undergo the pre-market approval process ("PMA"), *see* 21 U.S.C. § 360c(a)(1)(C), § 360e, described by the Supreme Court as "rigorous". *Riegl*, 552 U.S. at 316–317. All of the NexGen Flex system components at issue in this litigation went through a form of the 510(k) clearance process. (*See* Ulatowski Rep. at 20–25.)

Relevant here, the amount of time the FDA spends reviewing a device subject to the PMA process is significantly greater than the time spent reviewing the types of 510(k) submissions that Zimmer submitted for its NexGen Flex system components:

> The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. . . . As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."

Lohr, 518 U.S. at 478–79 (citations omitted). Because of the marked contrast in the amount of agency resources spent reviewing devices submitted through the PMA as opposed to the 510(k) review process, the Supreme Court has noted that the 510(k) process is "focused on equivalence, not safety," while PMA "is focused on safety, not equivalence." *Riegel*, 552 U.S. at 323 (emphasis removed). The 510(k) process is also different from PMA because under the 510(k) process, the FDA must find that a new device is "'substantially equivalent' to another device exempt from premarket approval" instead of making a determination regarding the safety and effectiveness of the device. *Reigel*, 552 U.S. at 317. The device is not "formally reviewed . . . for safety or efficacy," and the FDA "does not require that a device . . . take any particular

form for any particular reason" unlike the PMA process, which requires the device "to be made with almost no deviations from the specifications in its approval application. . . . " *Id.* at 323 (internal quotations omitted).

Importantly, a device may not be marketed in the United States until the § 510(k) applicant receives a letter declaring the device substantially equivalent, which "clears" the device to be sold. The regulations make plain that § 510(k) clearance does not constitute FDA approval of the device as safe and effective. 21 C.F.R. § 807.97. ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."). Instead, the FDA declares only that the device at issue is substantially equivalent to a device already on the market and may therefore be sold.

The court declines to admit the testimony of either expert concerning the extent to which 510(k) clearance establishes a device's safety and effectiveness. First, what 510(k) clearance does, and does not establish, is a legal determination reserved for the court. *See, e.g.*, *Good Shepherd Manor Found., Inc. v. Cty. of Momence*, 323 F.3d 557, 564 (7th Cir. 2003) ("The district court correctly ruled that expert testimony as to legal conclusions that will determine the outcome of the case is inadmissible."). This conclusion is bolstered by Ulatowski's unconvincing attempts to compare the 510(k) process to the PMA process (*see* Ulatowski Rep. at 27 ("In my experience . . . in virtually all categories a traditional 510(k) and PMA contain identical types of information."), as well as in his frequent citations to federal law and regulations governing the 510(k) clearance process. (Ulatowski Rep. at 27–40.) Samaras, too, cites sporadically to Supreme Court cases, federal statutes, and regulations, for his conclusion that the 510(k) clearance process "provides little protection to the public." (Samaras Rep. at 3–4.) In effect, both experts, using the same underlying legal landscape as a foundation, arrive at contrary conclusions pertaining to the legal effect of a 510(k) clearance determination. But legal

determinations are the province of the court, and to the extent this information is otherwise admissible, the court can inform the jury what a 510(k) clearance does and does not signify.

Second, assuming any expert testimony on the 510(k) clearance process would have probative value at Ms. Batty's trial (a matter not free from doubt), it is "substantially outweighed" by the danger of misleading the jury. *See* FED. R. EVID. 403. As the brief review of the differences between PMA review and 510(k) review outlined above suggests, there is significant risk that jurors may be led to believe that the 510(k) clearance that Zimmer's NexGen Flex system components received is equivalent to a finding of non-negligent design, which is an incorrect statement of law. *Cf. Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D.W. Va. 2014) ("That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims.") Put another way, the 510(k) clearance evidence that Zimmer has proposed could easily slide into an argument of "preemption-lite": Having cleared the NexGen Flex components through FDA, Zimmer suggests, it was not negligent. But that is precisely the argument the Supreme Court rejected in *Medtronic v. Lohr*, 518 U.S. 470 (1996), when it concluded that federal law does not preempt tort claims stemming from medical devices that were cleared through the 510(k) process. *See Riegel*, 552 U.S. at 321–323; *Lohr*, 518 U.S. at 501–02. In contrast, federal generally *does* preempt state law tort claims against devices that were cleared through the PMA process. *See Riegel*, 552 U.S. at 321–323.

In short, the FDA's finding of substantial equivalence, as a matter of law, is not a safety determination, and simply has too little probative value on the issue of whether the NexGen Flex system was defective, and whether those defects injured Ms. Batty. And beyond the concern that the testimony may be more prejudicial than probative, it appears all but certain that the testimony would create "undue delay" and create a trial within a trial. *See* FED. R. EVID. 403. Finally, neither expert's testimony is of the sort that "will help the trier of fact to understand the

evidence or to determine a fact in issue" in this products liability case, FED. R. EVID. 702(a), because, as explained, what the 510(k) process involves, and what it means, can be presented to the jury without the gloss of an expert's opinion.[13]

The court recognizes that there may be a basis for some limited consideration of Zimmer's compliance with FDA processes, if that evidence is relevant to the issue of punitive damages. An award of such damages under Pennsylvania law requires a showing of recklessness, *see Feld v. Merriam*, 485 A.2d 742, 747 (1984). Accordingly, if Zimmer is found liable, the court may consider allowing Ulatowski or Samaras to testify, on a limited basis, regarding Zimmer's pre- and post- market conduct to the extent such testimony bears on the overall reasonableness of the company's actions. But such a ruling at this point is premature. At this stage of the proceedings, the FDA's approval or nonapproval of the devices, standing alone, does not tend to prove that the devices were defective or unreasonably dangerous.

B. Warning Labels

Samaras and Ulatowski also discuss the accuracy of Zimmer's warning labels. For several reasons, the court concludes this testimony, too, should be excluded.

Samaras asserts that the labeling that Zimmer submitted in its 510(k) application "omitted important warnings in the labeling of the implants" (Samaras Rep. at 5), and that "[t]here is a pattern of inconsistency in the premarket notifications between the proposed intended use of the medical implant and the warnings in the package insert submitted to the FDA." (*Id.* at 44; *see also id.* at 54–56.) He proclaims that "[c]orrectly designed warnings consist of four (4) elements: (1) a signal word; (2) hazard information; (3) consequences of the harm; and (4) instructions for hazard avoidance." (*Id.* at 44 (citing Laughery and Wogalter,

[13] The court is not alone in reaching this conclusion. *See, e.g.*, *Bellew v. Ethicon, Inc.,* No. 2:13-cv-22473, 2014 WL 6680356 (S.D. W. Va. Nov. 25, 2014) (sustaining objections to testimony of Mr. Ulatowski in trial of an MDL products liability action, and observing: "[T]his court will not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process. . . . Mr. Ulatwoski's opinions relat[ing] to FDA regulations or procedures, FDA decision-making, FDA communications, or [defendant]'s compliance with such . . . are **EXCLUDED**.").

Handbook of Human Factors and Ergonomics: Warnings and Risk Perceptions 1174–97 (1997).) At his deposition, Dr. Samaras explained that he culled his definition of what constitutes "correctly designed warnings" from the textbook cited above, which is not specific to orthopedic devices; he is not aware of what standards apply to medical devices. (Samaras Dep. at 215:16–216:9.)

Undeterred by these limitations, Samaras cites language contained in Zimmer's 510(k) clearance application for its LPS-Flex device, in which Zimmer claims that "The LPS-Flex Fixed Bearing Knee provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range." (Samaras Rep. at 44–45.) This statement, Dr. Samaras continues, is "logically inconsistent" with the draft package insert Zimmer submitted elsewhere, which states that "[c]omplications and/or failure of the total knee prostheses are more likely to occur in: Patients with unrealistic functional expectations; Heavy patients; Physically active patients." (*Id.*) He makes similar criticisms of other proposed package inserts, and cites Zimmer's package brochure, claiming that it "depicts physically active persons," even though one of Zimmer's package inserts warns that "[e]xcessive physical activity and injury can result in loosening." (Samaras Rep. at 45–46.)

Dr. Samaras is not qualified to opine on Zimmer's labeling. He is not an orthopedic surgeon; he is an engineer. And as discussed above in the context of his opinions on design verifications, *see supra* at Discussion Part II.B.1.b, a lawyer or other educated layperson could make the same observations Dr. Samaras makes concerning the language used in these labels. Samaras admitted at his deposition that he is not qualified to write substantive knee implant device inserts about specific "surgical techniques or specific medical warnings," nor is he qualified to validate any labels actually chosen to accompany an orthopedic device. (*See* Samaras Dep. at 218:14–219:9; 220:22–221:5; 50:25–52:7.) In short, he has no "scientific, technical, or other specialized knowledge" that would "help the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702(a).

Plaintiff cites *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 925–26 (Pa. Super. Ct. 2011), in support of its argument that Samaras' labeling opinions are admissible. There, the court allowed a pharmacologist (not a physician) to testify concerning warnings, concluding that a Ph.D. in medical pharmacology and toxicology adequately qualified the witness as a "labeling expert." *Id.* at 925–26. The witness at issue also had more than twenty years of experience working to obtain FDA approval of more than 100 prescription drugs, and her responsibilities in securing those approvals included "revising drug labels in light of post-marketing safety signals." *Id.* at 926. Plaintiff argues that Samaras's advanced degrees in industrial and systems engineering and physiology are analogous to the qualifications of the pharmacologist in *Daniels*, and render him "qualified to express opinions about all labeling, including instructions for use, warnings and contraindications." (Pl. Resp. at 23.)

The court disagrees with Plaintiff for several reasons. For one, despite his criticisms of Zimmer's surgical technique instructions and warnings, Samaras has admitted that he is not qualified to write substantive knee implant device warnings or instructions himself, aside from limited "human factors" suggestions. (*See* Samaras Dep. at 220:22–221:16; Samaras Rep. at 44–45); *cf. Daniel*, 15 A.3d at 926 (pharmacologist's experience included revising warning labels based on communications with FDA). Nor is it clear that a pharmacologist's understanding of prescription drugs is analogous to an engineer's understanding of medical devices. Finally, Samaras broadly pronounces that all warning labels consist of the same types of "elements" mentioned earlier—a signal word, hazard information and potential consequences, and instructions for use. *See supra* at 23. He judges Zimmer's warnings against those standards, which he pulled from a textbook, *see* Laughery and Wogalter, *Handbook of Human Factors and Ergonomics: Warnings and Risk Perceptions* 1174–97 (1997). But that textbook is not specific to medical devices, and Samaras does not know whether the FDA or any other regulatory body would apply those standards to medical devices. (Samaras

Dep. at 216:2–18). This testimony does not appear to meet the standards of *Daubert* or Rule 702.

Ulatowski's proffered opinions on labeling require much less discussion. After walking through the FDA regulations related to product labeling, Ulatowski simply declares, "I examined Zimmer NexGen prescription labeling in the 510(k) documents. . . . In all cases the labeling meets the FDA prescription labeling requirements of [FDA regulations]." (Ulatowski Rep. at 76.) Simply proclaiming that something is compliant with FDA regulations, without more, has little value. Ulatowski does not even attempt to explain the basis for his conclusions which are, therefore, inadmissible.

C. Post-Market Vigilance Activities[14]

Dr. Samaras faults Zimmer for allegedly using a "defective complaint management system" that "severely limited the ability of employees to become of aware of events with patients from Zimmer implants" that had suffered injuries. (Samaras Rep. at 6.) Samaras is correct that the FDA's Quality System regulation requires companies to monitor their products after they are introduced into the marketplace. *See generally* 21 C.F.R. § 820.100. But a brief recounting of Dr. Samaras' opinions in this area reveals an inability to contribute "responsible testimony" on this issue, as well. *Tuf Racing Prods., Inc.*, 223 F.3d at 591. For example, he has harsh words for Zimmer's definition of a product complaint. Zimmer refers to such a complaint as a "communication that alleges deficiencies." (Samaras Rep. at 50.) The term "alleges" is unacceptable, Dr. Samaras asserts, because

> [t]his terminology ("allege"), unlike in the legal profession, is not normally used in everyday business communications. It subliminally informs Zimmer employees and Zimmer agents that the information is not wanted and, in any event, is only

[14] Dr. Samaras's supplemental report purports to evaluate over 23,000 complaints of Zimmer's devices and to discuss whether, based on this information, the company's complaint handling system was adequate. (*See* Samaras Supp. Rep. at 20.) Zimmer argues in its brief that the spreadsheet on which Samaras relies should be excluded at trial, but that it will "address this more fully in pre-trial motion practice." (Def. Samaras Reply at 14.) The court will reserve ruling on the spreadsheet's admissibility, or Samaras's interpretation of that data, at this time, but expects future arguments to be presented in a more focused manner.

> an allegation, not the real truth. This does not encourage individuals in a large organization to come forth with complaints about company products - even those complaints are phenomenological descriptions of clinical events (not root cause analyses) and are by definition the truth, not allegations.

(Samaras Rep. at 50.) Setting aside the complete lack of methodological support for this opinion, it is inconsistent with the governing federal regulation defining "complaint." Under that definition, "[c]omplaint means any written, electronic, or oral communication that *alleges deficiencies* related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution." 21 C.F.R. § 820.3(b). Dr. Samaras never cites the federal regulation, which Zimmer appeared to adopt in its own product complaint definition. HIs testimony appears to be nothing more than conjecture, whose probative value is substantially outweighed by its potential prejudicial effect. *See* FED. RULE OF EVID. 403. Dr. Samaras' opinion concerning Zimmer's complaint procedure will be excluded.

Mr. Ulatowski's account of Zimmer's post-market surveillance is likewise flawed. (*See generally* Ulatowski Rep. at 56–92.) His discussion simply summarizes internal Zimmer documents regarding post-market surveillance and declares that Zimmer "substantially complied with FDA post-market regulatory requirements, as evidenced by the compliant content of their post-market procedures and implementation of those procedures." (*Id.* at 56.) If the purpose of this testimony is to lay a foundation for introduction of Zimmer's records, Zimmer does not need an expert for this purpose, assuming those records are properly admissible at all. The objections to Ulatowski's opinions on this subject are sustained. And, as explained earlier, the court is unwilling to entertain testimony concerning Zimmer's FDA compliance in this context. *Cf. In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009) (affirming trial court's decision to strike the opinions of an FDA expert whose testimony "began with a brief overview of some federal regulations, followed by discussion of specific exhibits, largely devoid of regulatory analysis").

Again, the court recognizes that Zimmer's reasonableness in keeping its product on the market after issues with loosening became apparent may be relevant to Ms. Batty's claim under Pennsylvania law. *See In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3669933 at *34 (concluding that "[m]aterial fact questions remain[ed] concerning whether Zimmer exercised reasonable care designing its NexGen Flex knee, drafting warnings to accompany the device, *and other conduct associated with monitoring the device after it was placed on the market*"). The parties have not explained whether such evidence applies to Ms. Batty specifically, or otherwise, though. Absent specifics concerning the timing of post-market activities, the timing of Ms. Batty's surgery, and the information available to Zimmer, this post-market evidence will be excluded.

D. Adulterated or Misbranded Opinions

Finally, the court declines to permit Dr. Samaras to offer an opinion that the NexGen Flex knee implant series are "adulterated" and "misbranded" under the FDA regulations. (*See* Samaras Rep. at 5 (citing "Section 501(h) of the United States Food Drug & Cosmetic Act").) Legal opinions by experts are inadmissible. *See Good Shepherd Manor Found., Inc.*, 323 F.3d at 564. Dr. Samaras claims expertise in "human factors engineering, quality engineering and generally-accepted principles and practices of engineering" (Pl. Resp. at 24); he is not a lawyer nor an expert in FDA law. Notably, not even the FDA may "declare unilaterally that a label is false or misleading and thus that a drug is misbranded; it must proceed to court for a judicial determination in an enforcement action." *Tucker v. SmithKline Beecham Corp.*, 596 F. Supp.2d 1225, 1229 n.3 (S.D. Ind. 2008). Because this opinion is not admissible, Ulatowski's testimony rebutting it will not be allowed, either. (*See* Ulatowski Rep. at 106.)

CONCLUSION

Zimmer's motion to exclude the testimony of Dr. George Samaras, and Plaintiff's motion to exclude the testimony of Timothy Ulatowski, are granted in part and denied in part. Many of the opinions of these two experts will not be helpful to the jury or would fail Rule 403's balancing

test. To the extent evidence of Zimmer's conduct in developing the NexGen Flex system is otherwise admissible, it can be presented to the jury directly and does not require the aid of an expert witness.

The court may be willing to reconsider this ruling on a limited basis: some of the testimony the court has excluded may be relevant to the issue of the reasonableness of Zimmer's conduct. Such testimony may bear on a claim for punitive damages. With more specifics, evidence concerning Zimmer's post-market product monitoring may also be relevant to the underlying Pennsylvania state cause of action.

ENTER:

Dated: August 31, 2015

REBECCA R. PALLMEYER
United States District Judge